

DOCKET NO. 02F-0181

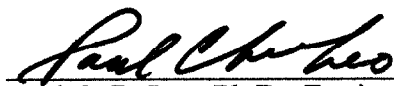
FINDING OF NO SIGNIFICANT IMPACT

FOR

Food Additive Petition 2A4736, submitted by Safe Foods Corporation, to amend the food additive regulations to provide for the safe use of cetylpyridinium chloride (CPC) as an antimicrobial agent to treat the surface of raw poultry carcasses in a system that collects and recycles the treatment solution.

The Environmental Review Group has determined that the approval of this petition will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by the petitioner in an environmental assessment dated October 4, 2002, and on a supplement to the environmental assessment prepared by the Environmental Review Group.

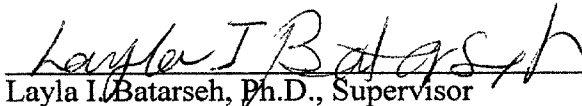
Prepared by



Date: February 26, 2003

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2002 F-0181

FONS 1

SUPPLEMENT TO THE ENVIRONMENTAL ASSESSMENT FOR FAP 2A4736

February 26, 2003

This document incorporates by reference the notifier's Environmental Assessment (EA) dated October 4, 2002.

This supplement to the EA for FAP 2A4736 provides additional discussion related to the environmental fate and effects of components in the notifier's antimicrobial solution Cecure™. Specifically, additional calculations regarding the environmental fate of cetylpyridinium chloride (CPC) are discussed.

Material Balance

CPC would be released to the environment as a result of the use and disposal of the treatment solution (Cecure™). The petitioner estimated a total market volume of CPC of 15,850 kg (35,000 lb). Of that, we estimate 6,100 kg would be released to the environment as a result of use. According to the petitioner, following its transit through the treatment cabinet and the drip tray, each chicken carcass (weighing approximately 3.3 lb. or 1.5 kg) will have approximately 3.55 mg of CPC on it. The petitioner estimates a maximum market capture of 20% for the total market of 8.6 billion chickens per year (1.72 billion chickens per year treated with Cecure™); therefore, the total quantity of CPC released to the environment as a result of its use on chickens is approximately 6,100 kg. The remaining 9,750 kg would be captured by the recycle system employed and disposed of by landfilling or incineration.

Releases may be broken down further according to that released as a result of consumption of chicken and that released as a result of further in-plant poultry processing. Before each carcass reaches the chill tanks, 1.01 mg of the 3.55 mg of CPC on each carcass will drip off into the offal stream. In the chiller tank, approximately 0.16 mg of CPC will be lost from each carcass. Subsequently, each carcass packaged for market will have about 2.38 mg of CPC ($3.55 \text{ mg} - 1.01 \text{ mg} - 0.16 \text{ mg} = 2.38 \text{ mg}$); therefore, for the 1.72 billion chickens treated with CPC, roughly 4,100 kg of CPC will be released to the environment as a result of their consumption. The total amount of CPC released as a result of processing (1.01 mg to offal + 0.16 mg to chiller = 1.17 mg per carcass) is approximately 2,000 kg.

Introductions and effects of CPC to the environment from use: Poultry processing

In the EA, the petitioner identified releases of CPC to aquatic and terrestrial environments that result from its use at poultry processing plants. Aquatic environments receive CPC in the effluent from the poultry plant wastewater treatment system. The petitioner stated that the

expected environmental concentration (EEC) is several orders of magnitude below the no effect level for relevant aquatic organisms.

Releases of CPC to terrestrial environments as a result of use may occur via three routes:

- 1) The treatment solution drips off the treated poultry following the treatment and capture unit, but prior to the chiller tank; the food additive is incorporated into poultry offal which is rendered into animal feed. Chickens consume the animal feed, and most of the CPC is not absorbed but passed by the animals into poultry litter;^[1] the poultry litter is used then as a soil amendment.
- 2) CPC partitions with dissolved air floatation (DAF) material that is generated during the treatment of the poultry plant wastewater; the DAF is used as a soil amendment.
- 3) CPC partitions with sludge that is generated during the treatment of the poultry plant wastewater; the sludge is used as a soil amendment.

The petitioner estimated an EEC of 2 ppb for soil treated with poultry litter, an EEC of 3.6 ppb for soil treated with DAF, and an EEC of 0.4 ppb for soil treated with sludge.

However, the environmental effects endpoints used by the petitioner for comparison were not relevant. These were oral toxicity data for mammalian species; more appropriate data would be for exposure of organisms that live in the soil by oral or dermal (surface) routes.

Unfortunately, there are no data available with regard to ecotoxicological effects of CPC and related compounds to such terrestrial organisms. However, one can estimate the terrestrial LC_{50} by applying safety factors to the aquatic toxicological data provided. The petitioner provided 24-hour LC_{50} values for several aquatic species that were in the range of 1,000 to 3,100 $\mu\text{g/L}$ (ppb). Using a 10-fold safety factor for the difference between aquatic species that are the subject of the studies and terrestrial species affected, and another 10-fold safety factor for the differences between aquatic environments and terrestrial environments, the LC_{50} values for terrestrial organisms would be estimated at 10 to 31 ppb. These values are several times higher than the highest EEC of 3.6 ppb.

Another way one may determine whether a significant impact to terrestrial environments will result from the approval of the food additive is to examine the area of land that is affected by the introductions. For soil amended with poultry litter, the petitioner estimated that 2,000 kg of CPC would be lost to the offal and would ultimately find its way into chicken feed; CPC

¹ Craig, C.R. and Stitzel, R.E. Oral exposure: Quaternary ammonium compounds are poorly absorbed by oral route. In: *Modern Pharmacology*, 4th edition. Boston: Little, Brown and Co. 1994.

would be excreted into litter which would be amended into soil. The petitioner estimated the concentration of CPC in litter at 0.30 mg/kg. Therefore, the total quantity of poultry litter with CPC would be as follows:

$$\begin{aligned}\text{Total poultry litter with CPC} &= (2,000 \text{ kg CPC}) \times 10^6 \text{ mg/kg} \div 0.30 \text{ mg/kg CPC in litter} \\ &= 6.67 \times 10^9 \text{ kg litter}\end{aligned}$$

The petitioner indicated that litter is amended to soil at a rate of 1.1 kg/m², subsequently 6.06 × 10⁹ m² potentially would be affected, or about 606,000 hectares (1.5 million acres). The United States Department of Agriculture estimates that there are currently over 900 million acres of land in farms and approximately 470 million acres in cultivation. Therefore, less than 1% of the cultivated land in the US potentially would be affected by amending of soil with poultry litter containing CPC.

For soil amended with DAF material, the petitioner estimates that a facility processing 200,000 chickens per day would generate 16,000 kg of DAF;^[2] subsequently, the total amount of DAF generated per year if 1.72 billion chickens are treated with CPC is 137,600,000 kg. The petitioner assumes a 2.5% dilution rate, which is equivalent to an application rate of 45,000 kg/hectare. So, about 3,000 hectares of land would be affected, or about 7,500 acres.

For soil amended with sludge from poultry plant wastewater treatment facilities, the petitioner estimates that a facility processing 200,000 chickens per day would generate 1,736 kg of sludge;^[3] subsequently, the total amount of sludge generated per year if 1.72 billion chickens are treated with CPC is about 15,000,000 kg. The petitioner assumes a 2.5% dilution rate, which is equivalent to an application rate of 45,000 kg/hectare. So, about 333 hectares of land would be affected, or about 825 acres.

Only negligible areas of land would be affected by soil amendment with DAF (7,500 acres) or poultry plant sludge (825 acres). A greater quantity of land might be affected by application of poultry litter (1.5 million acres) but this is still a small portion of the total cultivated land in the US.

² Page 22 of the October 4, 2002, environmental assessment.

³ Page 23 of the October 4, 2002, environmental assessment.

Introductions and effects of CPC to the environment from use: Poultry Consumption

The petitioner did not calculate an environmental introduction concentration (EIC) for CPC as a result of consumption of chicken bearing residual CPC. Since this represent two-thirds of the amount of CPC released to the environment as a result of use, the EIC is estimated using the following calculation:

EIC--Aquatic (ppm) = A x B x C x D, where:

A = kg/year, as CPC residue on chicken

B = 1/liters per day entering POTWs (1.22×10^{11} liters per day)^[4]

C = year/365 days

D = 10^6 mg/kg (conversion factor)

Therefore, assuming a worst-case situation where no CPC is absorbed following consumption^[5] and 100% is released to wastewater treatment plants and ultimately to receiving waters:

$$\text{EIC} = 4,100 \text{ kg} \times (1/1.22 \times 10^{11} \text{ liters per day}) \times (\text{year}/365 \text{ days}) \times 10^6 \text{ mg/kg}$$

$$\text{EIC} = 0.000 \text{ 092 mg/L} = 92 \text{ ng/L (ppt)}$$

Given the very low EIC estimated, an EEC can be estimated simply by assuming a 10-fold dilution of treated effluent to a receiving water body. Subsequently, the EEC would be 9.2 ng/L

Summary

The use of a capture and recycle system for the application of Cecure™ (CPC) to poultry will result in greatly reduced releases of CPC to the environment compared to application without it. The petitioner initially estimated a use of Cecure™ for poultry processing of 2.5 million

⁴ The flow of wastewater to POTWs in the United States is 32,175 million gallons per day (1.22×10^{11} liters per day). Table C-3, Appendix C, 1996 Clean Water Needs Survey, U.S. Environmental Protection Agency, viewed on the Internet at: <http://www.epa.gov/OWM/toc.htm> on June 8, 2002.

⁵ Craig and Stitzel, *Op. cit.*

pounds per year.^[6] This estimate assumed a 30% market penetration. However, we estimated a use (and release to the environment) of 1.5 million pounds per year of CPC based on the current estimate of 20% market share and the petitioner's use rate described in the March 20th submission. For the treatment system using capture and recycle technology described in the revised EA, we estimate a total release to the environment of 13,500 lb (6,100 kg) at concentrations well below levels of ecotoxicological concern. That is a reduction of greater than 99% in releases of CPC to the environment.

⁶ Page 19, EA dated March 20, 2002.